

RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects in Navy Research

Volume 1, Number 3

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1 May 2006

Comment

Time for Training

The DON HRPP team has finished developing a new human research protections training package for commanding officers (see article, page 4). The package, when released this summer, will be accessible through the CITI (Collaborative Institutional Training Initiative) home page (www.citiprogram.org).

The commanders' training module represents the start of a long-term Navy HRPP effort to train Navy unit leaders and others responsible for research protections in ways that zero in on their unique roles and responsibilities for protecting human subjects. It will give them the answers they need to carry out those responsibilities, without becoming a burdensome distraction from their command missions.

The new look for commanders' training is based on the recognition by the DON HRPP team that human research protections for the Navy is facing new realities and new demands. The standup of the program, after all, emerges from a top-down reorganization of the Navy's, and DoD's approach to protecting research subjects. The Under Secretary of the Navy's Executive Decision Memorandum of

April 29, 2005 directed a strategic shift in the Navy's HRPP organization and focus, based on the designation of the Navy Surgeon General as the single point of accountability. That shift recognizes the urgent need for change, directed by the Director, Defense Research & Engineering.

That direction extends explicitly to training. The DON HRPP team recognizes, as it works to infuse commanders and staffers with a sharper sense of the HRPP requirement, that training often is perceived as complex, time-consuming, and disconnected from the real-world demands of running a Navy unit. That is, a low-priority bureaucratic chore that robs commanding officers (COs) of scarce time and doesn't convey the critical value to their operational missions of an effective HRPP program.

The new CO training module confronts those shortcomings head-on. The terse introduction lays out in its opening sentences the real-world responsibility of commanders for protecting subjects in research. It stresses that a command or institution with an Assurance, after all, has pledged to protect the human subjects who participate in its re-

search projects. The module reminds commanders that their Institutional Review Boards provide them with guidance on approving research protocols based on whether the research can be carried out in compliance with research protection requirements.

The CO training module is taut and austere, and focuses on real-world issues. It will serve as a baseline for subsequent HRPP modules for researchers, IRB staffers, and all who work in Navy research. It will provide the nuts-and-bolts initial and continuing training they require in a lean, no-nonsense format that acknowledges the challenges of managing Navy research to meet critical needs—while allowing no compromise on protection for the human subjects who support that research.

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Medical Center Research Competitions

Mao, Weis, Provencher Claim NMC Research Awards

The Navy's medical centers last week announced the winners of their annual research competitions. Lt. Chad Mao of the National Naval Medical Center, Bethesda, Md., Lt. Cdr. Daniel Weis and Cdr. Gail Manos of Naval Medical Center, Portsmouth, Va., and Lt. Cdr. Matthew Provencher of Naval Medical Center San Diego were among those named top Navy medical researchers for the year.

The two top winners in the CIP category from each command will compete in the Navywide research competition set for 12 May at NNMCMC Bethesda.

This year marks the 21st anniversary of the Navy's series of medical research competitions. Many winners since the first competitions in 1986 have risen to senior leadership positions in Navy medicine.

Entries are designed for either poster or podium presentation, in three categories: (1) Clinical Investigation Program (CIP) (staff and resident); (2) Research Other than CIP; and (3) Case Reports. Awards are offered both for staff and resident levels. Winners at the medical centers include:

NNMCMC Bethesda:

Category 1: Resident level: 1st place - Lt. Chad Mao; 2nd place - Lt. Randy Bell. **Staff level:** 1st place - Cdr. Brooks Cash; 2nd place - Cdr. James Dunne.

Category 2: Resident level: 1st place - Lt. Mat-

thew Needleman; 2nd place - Lt. Tamara Kindelan.

Staff level: 1st place - Lt. Cdr. Dong Lee; 2nd place - Cdr. Brooks Cash.

Category 3: Resident level: 1st place - Army Capt. Elizabeth Burchard; 2nd place - Lt. Marilisa Gibellato. **Staff level:** 1st place - Lt. Cdr. Robert Morgan; 2nd place - Capt. Craig Womeldorph.

NMCMC San Diego:

Category 1: Resident level: 1st place - Lt. Tammy Jansen; Runner-up - Lt. Matthew Patterson. **Staff level:** 1st place - Lt. Cdr. Matthew Provencher; Runner-up - Lt. Cdr. Song Kang.

Category 2: Staff level: 1st place - Lt. Cdr. Eugenio Lujan; Runner-up - Lt. Cdr. Daniel Solomon.

Category 3: 1st place - Lt. Cdr. David Krause; Runner-up - Cdr. Elizabeth Hofmeister.

NMCMC Portsmouth:

Category 1: Resident level: 1st place - Lt. Daniel Weis, Cdr. Gail Manos; 2nd place - Lt. James Callan, Cdr. Mark Kostic, and Cdr. E.A. Bachrach; 3rd place - Lt. Nazima Kathiria, Cdr. Timothy Shope. **Staff level:** 1st place - Capt. Richard Westphal, Lt. Sean Convoy, and Warren Clark; 2nd place - Capt. Richard Westphal, Cdr. William Goodman, and Cdr. Robert Amaya; 3rd place - Cdr. Amy O'Boyle, Lt. Joy Greer, and Capt.

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NMCMC San Diego winners, left to right: Lt. Cdr. Song Kang, Cdr. Elizabeth Hofmeister, Lt. Cdr. Eugenio Lujan, Lt. Tammy Jensen, Rear Adm. Brian Brannman, Lt. Cdr. David Krause, Lt. Cdr. Daniel Solomon, Lt. Cdr. Matthew Provencher, Lt. Matthew Patterson.

SYSCOMs Looking to Protect Human Subjects

The laboratories of the Navy's Systems Commands (SYSCOMs) that conduct critical research on fleet ship, aircraft, and weapon systems are moving rapidly to apply the principles of human-systems integration (HSI) to their programs.

As they do so, they're recognizing the critical importance of protecting human subjects in research.

Any Systems Command laboratory that is considering initiating research projects on human-systems integration that will involve human subjects is required to apply for an Assurance from the DON HRPP, and arrange for an Institutional Review Board (IRB) to evaluate research proposals. Commanding officers and others involved in research with human subjects at the SYSCOMs and fleet and training commands also are required to go through HRPP training.

The Surgeon General of the Navy approves and renews Assurances. The SG has delegated to the Chief of Naval Research (CNR) responsibility for oversight and monitoring of compliance with human research protections by the SYSCOMs, as well as by the training and operational commands. The Office of Naval Research's Human Research Protections Division (ONR 343), led by acting director Dr. Tim Singer, executes CNR's oversight and compliance functions.

The DON HRPP now is discussing human research protection policy with several Navy and Marine Corps commands that conduct human research, including the Naval Research Laboratory in Washington, D.C., and the Naval Air Warfare Center (NAWC) Training Systems Division in Orlando, Fla., among others.

The Naval Sea Systems Command (NAVSEA), headquartered in Washington, D.C., oversees ship-systems acquisition programs. The Naval Air Systems Command (NAVAIR), based at Patuxent River, Md., manages naval aviation programs.

NAVSEA and NAVAIR are collaborating to stand up a Navy-wide Human Systems Performance Assessment Capability (HSPAC) that will evaluate the effectiveness of systems-design efforts focused on sailor

performance.

Greg Maxwell, deputy commander of NAVSEA's HSI directorate, says that the HSPAC will analyze and certify the sailor-performance aspect of ship-systems development to maximize the benefits of human-systems integration for future platforms.



A Navy F/A-18 Hornet fighter/attack aircraft takes off from the carrier Dwight D. Eisenhower during an Atlantic Fleet exercise.

Currently, NAWC's Aircraft and Training Systems Divisions hold Assurances. The only NAVSEA commands now holding Assurances are the Undersea Warfare Center, Newport, R.I., and the Navy Experimental Diving Unit, a tenant command of the NSWC Dahlgren Division's Panama City, Fla. Station.

The Naval Surface Warfare Center Dahlgren Division (NSWC Dahlgren) currently is rewriting its corporate instruction to address the need for an IRB to review research protocols proposed by division researchers. Initially, the command would use the NAWC Aircraft Division IRB when required, provided through the HSPAC. Eventually, if stipulated by the new corporate instruction, Dahlgren will establish its own IRB.

Check Us Out! The Office of Naval Research, Research Protections Division's website is now at

http://www.onr.navy.mil/sci_tech/34/343

HRPP Training

DON HRPP Team Readies Commanders' Training Module

Commanding officers of ships, shore facilities, medical treatment facilities, R&D labs, and training commands all face tough demands on their time. Training competes with numerous other requirements.

To heighten COs' awareness of work that involves humans as research subjects, the DON HRPP has developed a training module tailored expressly for them. The web-based module, to be available 24/7, presents key points that COs "need to know." The module will be available through the CITI website late this summer.

The module traces delegation of authority from DoD's Director, Defense Research & Engineering (DDR&E) through the Navy Surgeon General, the single point of accountability for the Navy's human research protection program, to Navy COs at commands conducting research with humans. The module emphasizes that protecting human research subjects is an "all hands" effort at Navy commands. It describes the requirements for a human research protection program: the written "promise" — called an Assurance of Compliance — to follow the ethical and regulatory require-

ments; research ethics training program; scientific review process; review by an Institutional Review Board (IRB); and monitoring research after it is started.

Two hard-hitting paragraphs alert COs to the potential for undue influence on military and civilian personnel to participate in research. A succinct format introduces COs to critical concepts: medical monitors for "risky" research; providing care to "make whole" subjects injured during research; considerations for international research; and FDA requirements.

"Minors in the Military" and "Women in the Military" paragraphs invite COs' attention to nuances unique to the research setting. COs learn the limitations on research with prisoners; the prohibition of research with POWs or detainees; and the requirements for classified research.

***Write to us! The DON HRPP now
has a direct email address:
humanresearch@us.med.navy.mil***

HRPP Staffers Elliott and Scannell at CITI

The April 2006 meeting of the 40-member CITI Developers Group found DON HRPP staff member Marianne Elliott leading a group preparing a new research misconduct module and Pat Scannell working on a biomedical refresher course. Elliott and Scannell drafted the COs' training module (see article, above).

The Developers Group emerged first in October 2000 when 11 colleagues met to create a web-based training program on human subject protections for their own investigators.

The Group now meets twice a year to develop annual refresher courses and revise current modules used by over 600 institutions including universities and the VA. The developers take user feedback seriously and improve courses based on comments and suggestions (and complaints!).

More than 300,000 individuals in the U.S., Europe,

Africa, Asia, and Australia have completed CITI courses. The initial course of 12 biomedical-oriented modules is complemented by 11 social-behavioral modules and a handful of general-interest modules. The international site includes modules in Spanish and Chinese.

Look for modules on public health research, students as researchers and subjects, and IRB administration. CITI is also developing two courses: GCPs — "Good Clinical Practices" and RCR — "Responsible Conduct of Research."

The GCP course covers investigational agents, adverse event reporting, working with industry, and monitoring clinical research. The RCR course addresses mentoring, authorship and publication, animal care and welfare, and aspects of collaborative research.

Research Competition Winners Named

(Continued from page 2)

Leo Kusuda.

Category 2: Resident level: 1st place - Lt. Cdr. Christopher Duplessis, James Miller, Lt. Cdr. Loring Crepeau, Lt. Christopher Osborn, and Lt. Jeff Dyche; 2nd place - Lt. Christopher Ennen, Capt. Everett Magann; 3rd place - Lt. Cdr. Christopher Duplessis, David Fothergill, Lt. Jeff Gertner, Derek Schwaller (Naval Submarine Medical Research Lab, Groton, Conn.).



NNMC Winners Lt. Chad Mao, Cdr. Brooks Cash

Staff level: 1st place - Capt. Everett Magann, Michael Paech, Dorota Doherty, Lt. Amy Niederhauser, Lt. Christopher Ennen, and John Newnham; 2nd place

- Lt. Cdr. John Whitcomb; 3rd place - Capt. Kevin Knoop, Lt. Joseph Buglisi (Battalion Aid Station, Combat Logistics Regiment 25, Camp Lejeune, N.C.), Army Capt. Marc Levsky (Dept. of Emergency Medicine, Darnall Army Community Hospital, Fort Hood, Tex.), and Lt. Cdr. Michael Euwema (Dept. of Emergency Medicine, Naval Hospital, Jacksonville, Fla.).

Category 3: Judges Panel 1: 1st Place - Lt. Jennifer Barger, Lt. Cdr. David Allen, Capt. Barton Gumpert, Cdr. Jeffrey Timby, and Lt. Cdr. Clayton Smiley; 2nd place - Lt. Grace Freier, Lt. Allen Wright (Marine Corps Recruit Depot, Branch Medical Clinic-Navy Hospital Beaufort, S.C.), Gregory Nelson, Eric Brenner (South Carolina Dept. of Health and Environmental Control), Sundari Mase (Calif. Dept. of Health), Capt. Sybil Tasker (National Naval Medical Center), Lt. Cdr. Karen Matthews, and Capt. Bruce K. Bohnker (Ret.) (Navy Environmental and Preventive Medicine Unit-2); 3rd place - Lt. Cdr. R. Lee. Biggs, Lt. Amy Niederhauser, and Lt. Cdr. Jeanne Busch. **Judges Panel 2:** 1st Place - Lt. R. Holmes, Lt. Cdr. C. Smiley; 2nd Place - Lt. Tod Morris, Cdr. Michael Hopkins; 3rd Place - Lt. Jessica Lee, Cdr. Michael Hopkins. **Staff:** 1st Place - Lt. Cdr. Jeff Feinberg. **Concurrent Categories (Wellness):** Lt. Cdr. Gilbert Seda, Cdr. Treyce Knee, Lt. Jennifer Burke, and Lt. Cdr. David Allen. **Concurrent Categories (Readiness):** Lt. Cdr. Christopher Duplessis, James Miller, Lt. Cdr. Loring Crepeau, Lt. Christopher Osborn, and Lt. Jeff Dyche.

SAVE THE DATE!

November 14, 2006

**Human Research
Protection Programs:
DoD Unique Perspectives
Washington, DC**

Come to a day of training devoted to discussing current DoD issues in Human Research Protection.

This training is open to DoD Institutional Officials (military, civilian, and contractor), IRB office staff and members, Researchers and staff, and Component Oversight Officers.

To be held in association with the 2006 PRIM&R - ARENA Annual HRPP Conference.



HRPP Questions and Answers

Who Can Be a PI?

Who can be a principal investigator (PI) in DON-supported human subject research?

There have been differences between Clinical Investigation Program (CIP) and Research and Development (R&D) with regard to PI status. The Navy's new human research protection instruction, SECNAVINST 3900.39D, now awaiting signature, unifies all human research protection requirements under one policy and defines PI.

Principal Investigator (PI): In DON-supported human subject research, an individual who possesses the required education, knowledge, skills, experience (credentials) to initiate, conduct and oversee human subject research, and has completed the required research ethics training including human subject protections. In addition:

For DON-supported Intramural Research: A Principal Investigator must be a current federal employee (uniformed or civilian, staff, or trainee), an individual covered under the Intergovernmental Personnel Act, or a consultant consistent with the requirements established by 5 USC 3109, and must be assigned to or employed by a specific command. Status as a contractor or federal retiree alone is not sufficient to qualify individuals as principal investigators for such research.

For DON-supported Extramural Research: A Principal Investigator must meet the criteria established by the institution that receives the award.

Is it permissible to list "English speaking" (or "non-English speaking") in the inclusion criteria of research protocols?

Using language or speaking skills as exclusion or inclusion criteria in research protocols for ease of recruiting and selecting subjects would not be in keeping with the Belmont Report principles of respect for persons and justice, or the federal regulations that require consent information be given to subjects or their representatives in a language understandable to them.

One may make a decision that a potential subject is not eligible to enroll in the research due to not understanding or comprehending the information in order to make an informed decision, despite one's efforts. This decision must be based on an assessment of comprehension and be clearly documented in research files and could apply to any research subject regardless of language.

Every effort should be made to present information and consent documents to subjects in a language understandable to them. There is an alternative that permits oral presentation of informed consent information in conjunction with a short-form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

For further information see: <http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>



Arleigh Burke-class Aegis destroyers Russell (left) and Shoup underway in the South China Sea.